K082727

FEB - 6 2009

X. PREMARKET NOTIFICATION SUMMARY

Submitted by:

Vitrolife Sweden AB
Faktorvägen 13
SE-434 37 Kungsbacka
SWEDEN

Contact Person:

Mr Kjell Kjörk
Vitrolife Sweden AB
Faktorvägen 13
SE-434 37 Kungsbacka
SWEDEN
Phone +46 31 721 80 77
Fax +46 31 721 80 90
Mail kkjork@vitrolife.com

Date Prepared:

5 February 2009

Trade Name:

Follicle Aspiration Set, Reduced Single Lumen

Common Name:

Follicle Aspiration Set

Classification Name:

Assisted Reproduction Needles
(21 C.F.R. § 884.6100)

Predicate Device:

Follicle Aspiration Set (K991273)

Description of the Device:
The Follicle Aspiration Set, Reduced Single Lumen device is a modification of the current Vitrolife Follicle Aspiration Set (K991273). The Follicle Aspiration Set, Reduced Single Lumen has the same intended use as the predicate device (K991273), and similar technological characteristics related to safety and effectiveness.

The predicate device Follicle Aspiration Set (K991273) has a broad 510(k) clearance covering single lumen, double lumen and Luer lumen. The device is intended to be used to obtain gametes from the body.

A thinner type of needle end is being introduced, and the last 40-60 mm close to the tip of a standard needle is reduced from an inner diameter of 1.2 mm to an inner diameter of 0.6 mm.

Intended Use
Follicle Aspiration Set, Reduced Single Lumen is intended for flushing and/or aspiration of oocytes from ovarian follicles

Technological Characteristics:
The Follicle Aspiration Set, Reduced Single lumen device is a modification of the current Vitrolife Follicle Aspiration Set (K991273). The Follicle Aspiration Set, Reduced Single Lumen has the same intended use as the predicate device (K991273), and similar technological characteristics related to safety and effectiveness.

A thinner type of needle end is being introduced, and the last 40-60 mm close to the tip of a standard needle is reduced from an inner diameter of 1.2 mm to an inner diameter of 0.6 mm.

The main safety concern regarding this change is the risk of the reduced part of the needle breaking off during the procedure as noted in the risk analysis. However, the needle has undergone testing according to ISO 9626 with respect to resistance of tubing to breakage in order to verify the safety in this aspect. The needle has also been tested with the resistance test to an extended angle and passed. It should be noted that the wall of the reduced part is at least 50% thicker than the wall of the standard part. This is the logical consequence of the manufacturing method where the same cross-sectional area is kept from the standard part to the thinner, reduced part.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 2009

Mr. Kjell Kjörk
Pharmacist, Regulatory Affairs Manager
Vitrolife Sweden AB
Box 9080 SE-400 92 Göteborg
SWEDEN

Re: K082727
Trade/Device Name: Follicle Aspiration Set, Reduced Single Lumen
Regulation Number: 21 CFR §884.6100
Regulation Name: Assisted reproduction needles
Regulatory Class: II
Product Code: MQE
Dated: January 22, 2009
Received: January 23, 2009

Dear Mr. Kjörk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

XI. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K082727

Device Name: Follicle Aspiration Set, Reduced Single Lumen

Indications for Use: Follicle Aspiration Set, Reduced Single Lumen is indicated for flushing and/or aspiration of oocytes from ovarian follicles

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the Counter Use _____
(Per 21 C.F.R. § 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K082727